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February 16, 2000

Docket Clerk
Attn: Docket No. OST-99-6578 - 21
Department of Transportation
400 7th Street SW, Room PL401
Washington, DC 20590

Dear Sir or Madam:

DrugProof is one of the HHS certified laboratories performing DOT drug screens on a daily basis. The publication of the Notice of Proposed Rule Making (NPRM) for 49 CFR Part 40 has prompted us to submit the following comments regarding this document. While many provisions and clarifications of the current rules are excellent, there are other areas of concern.

Comments:

1. §40.33 Provisions for Collector training and documentation are very good and should help improve this currently problematic area.

2. §40.47 The requirement that the DOT form never be used to collect a non-DOT specimen is a problem. Because of the number of collections that are performed when the type of collection required is unclear – especially in post-accident situations for employers with both DOT and non-DOT covered employees- the collector and donor frequently do not know whether a specimen should be a DOT or non-DOT.

   Our guidance to collectors in the past has been to use the DOT collection protocol (the most stringent) when the situation was confused and if the test was a non-DOT, 'downgrade' the specimen to non-DOT with the informed consent of the donor. This currently happens 3-4 times per week.

3. §40.91 Requiring specific adulteration tests is probably not a good idea. The adulterants available change on a weekly to monthly basis. Nitrites were big last year, but are seen much less often today. Acid (e.g. UrineLuck I) and base adulterants are now seldom seen. Pyridinium Chlorochromate (e.g. UrineLuck II) was very prevalent 6 months ago, but now other chromate compounds (e.g. UrineLuck III) are coming to the fore. Additionally, there are no 'FDA approved ' methods for any of the adulterants at this time.

   The process of adulterant chemists dreaming up new adulterants and labs trying to find ways to detect the adulterants moves very quickly. Requiring testing for adulterants that were popular last year is not effective. Requiring some form of testing for specimen validity is a good idea, however. Creatinine/Specific Gravity help with dilute specimens. All the labs continue to scramble to keep up with the adulterant chemists in the detection of adulterants.

The idea of actively trying to catch all or most attempts to cheat would mean a change in direction for the DOT program. It has frequently been called a 'deterrent program, not a detection program'. The emphasis on searching for adulterants leads to the labs spending more time trying to detect attempted adulteration than deterring drug use/abuse. Perhaps stringent deterrents for proven adulteration would be more effective and more in line with the historical DOT program.

4. §40.93 The definition of SUBSTITUTED specimens is scientifically problematic. Having seen the data on which this definition is based, we feel that the position DOT has taken is extreme and not founded on sufficient scientific evidence.

   We have performed very limited urine dilution experiments in this lab and found that a urine of ~5 mg/dL and specific gravity of 1 .001 can be produced by a normal donor after extraordinary consumption of water. Also, we are concerned about poorly controlled, diabetic donors who may produce a very dilute urine with a high specific gravity, due to glucose spill, may then fall into the 5mg/dL creatinine and 1.020 specific gravity category. We suggest that more research specifically directed at these criteria be carried out.

   We are also very concerned about confusion which arises when laboratories are directed to comment on substituted specimens using the phrase "not consistent with normal human urine." Many employers believe this means that animal urine or some other non-human source of sample was supplied. We believe this is rarely the case and suggest that a less judgmental explanation be used such as "specimen grossly dilute and not acceptable for program purposes." We feel that positive drug findings should be reportable for such specimens and that "test not performed" should not be marked.

5. §40.111 – Appendix B The requirement to provide statistics by reason for test is onerous to the laboratory and not very helpful to the employer. The statistics provided by the labs include the positive results for all specimens tested, including blinds and those **not** verified by the MRO. The statistics that are valuable to the employer are those provided by the MRO/service agent which only include true positives.

   The change from quarterly to semi-annual DOT statistical reports is OK, however, the statement which allows for additional reports based on agency is frightening. All DOT modalities should have the same requirements for statistical reports.

6. §40.109 The requirement for 5 years retention of records is unnecessary. For this lab this would mean the retention and administration of over 5,000 boxes of records instead of the current 2,000. Because of the stringent security and access requirements of the HHS Guidelines, this would mean a very significant increase in doubly secure storage space and cost. Requiring only positive records to be maintained for an extended time does not significantly affect the amount of records stored, since the positives are intermixed in batches with negatives, all records must be kept. The only records that could be discarded separately would be the negative Custody and Control Forms, but this is a small part of the total.

This lab has never had a request for documents more than 14 months old. The current requirement of record maintenance for 24 months is perfectly adequate. We maintain records indefinitely for cases in litigation/arbitration (i.e. those cases for which litigation packages have been requested), and this may be a reasonable requirement.

7. **§40.121** The requirement for MRO training/certification is a good idea. There are still practicing MROs who are not following DOT procedures.

8. **P 18 of NPRM** Standards for adulteration retest criteria are difficult. Similar to drug retest criteria, the adulterant retest requirements need to reflect that the adulterants may not be stable in the urine specimen. 'Re-confirmation' of an adulterant should be based on presence, not quantitative result.

9. **§40.175** Short term refrigerated storage of the split specimen should not be required. HHS guidelines allow up to 7 days room temperature storage of specimens from collection to testing, based on expected stability of drugs in the specimen.

   Virtually all labs process the vast majority of specimens in 24-48 hours. Many labs do not have refrigerated storage space for all specimens. To refrigerate just the split would require separation of the split and primary specimen. This is risky, would require a significant amount of administration and may lead to the inadvertent discard of a split.

10. **§40.215, §40.61, §40.65, Definitions** The requirement for a DER for all employers, while a helpful, good idea, will be a problem for collectors/BATs (and labs). Very frequently collectors/BATs are faced with collection of specimens for companies of which they have never heard. Similarly, labs frequently receive specimens from an unknown employer with perhaps only an MRO identified.

    §40.61 Similarly, requiring the collector to report to the DER that a donor did not come at a scheduled time is not consistent with how things happen. Collections are seldom scheduled, the donor simply appears at the collection site.

    §40.65 Again, notification of the DER of all collection problems is frequently difficult.

11. **§40.25** The requirement to inspect pockets and boots seems extreme. Many of the DOT covered employees are workers and wear boots. While it is possible to smuggle adulterant material in pockets and boots, it is just as easy to smuggle it in underwear – which cannot be searched. This seems difficult and contentious.

Sincerely,

Arthur M. Zebelman, Ph.D.
Scientific Director, Responsible Person

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